European Food Safety Authority

Guidance Document on Risk Assessment for Birds and Mammals Suggested Structure of the Revised Guidance Document

Andreas Höllrigl-Rosta, Umweltbundesamt; Germany

Preparation of GD

Sub Group Modelling Approach

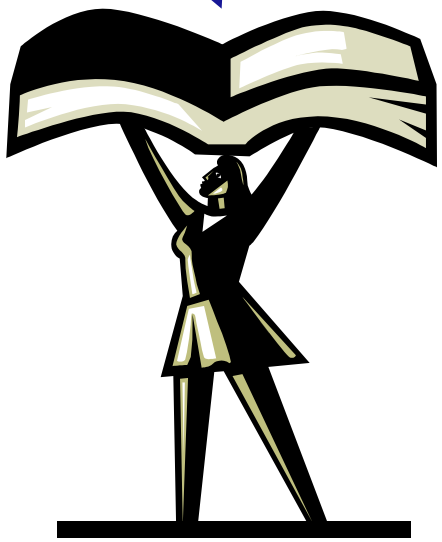
Sub Group Long-term RA

Sub Group Residues

Sub Group Ecological Parameters

Core Group

Your input



Main structure

Core document

- all relevant data and information for tier-1 assessment
- all basically relevant guidance on methodology for refined risk assessment

Background document

- scientific background for approaches, models and default values

Supplementary document

- information considered during developing new guidance,
- information for risk managers
- not required for daily assessment work

Introduction

- This document intends to provide guidance to applicants/notifiers and Member States on how to conduct a risk assessment for birds and mammals in the context of the evaluation of active substances for inclusion in Annex I of Directive 91/414/EEC as well as in the context of authorisation of plant protection products.
- The scope of the document is to elucidate in particular the “unless” clause of Annex VI of Directive 91/414/EEC

Principles of the risk assessment

- Risk characterisation
  - General principles of deriving risk descriptors
  - Relevant TER values for the assessment
  - Tiered approach: screening step – refined risk assessment
  - Alternative approach using empirical model?
- Toxicity figures
  - Acute toxicity to birds
  - Acute toxicity to mammals
  - Long-term/reproductive toxicity to birds
  - Long-term/reproductive toxicity to mammals
- Exposure estimate
  - Calculating exposure for the theoretically-based approach (ETE)

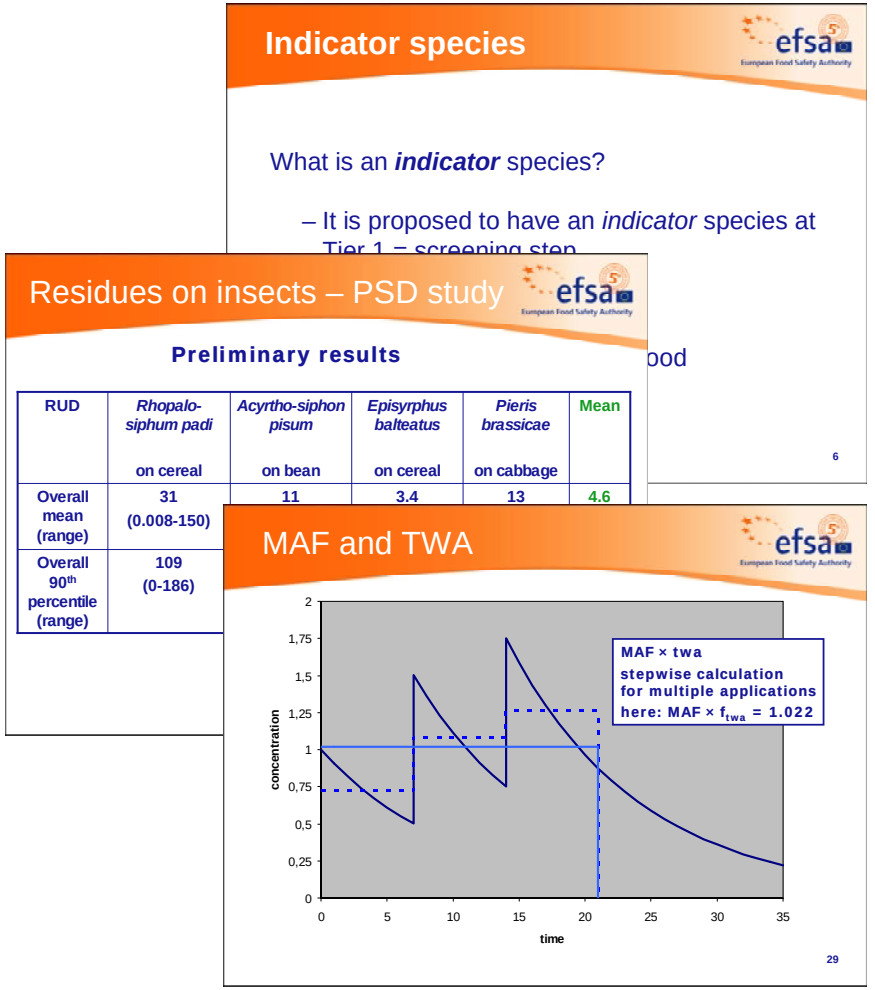
RA using ETE model

- General approach and default values for the tier 1
- Establishment of basic tier-1 scenarios for spray applications
- Establishment of basic tier-1 scenarios for non-spray applications
- Bioaccumulation and food chain behaviour

Tier 1

Spray applications

- Grouping of crops, definition of model species with worst-case exposure via diet and other routes
- Default RUD values for food items
- Multiple applications and time-course of environmental residues
- Factors for other exposure routes than dietary uptake



Indicator species

What is an ***indicator*** species?

– It is proposed to have an *indicator* species at Tier 1 = screening step

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Residues on insects – PSD study

Preliminary results

RUD	*Rhopalo-siphum padi* on cereal	*Acyrtho-siphon pisum* on bean	*Episyrphus balteatus* on cereal	*Pieris brassicae* on cabbage	Mean
Overall mean (range)	31 (0.008-150)	11	3.4	13	4.6
Overall 90th percentile (range)	109 (0-186)				

MAF and TWA

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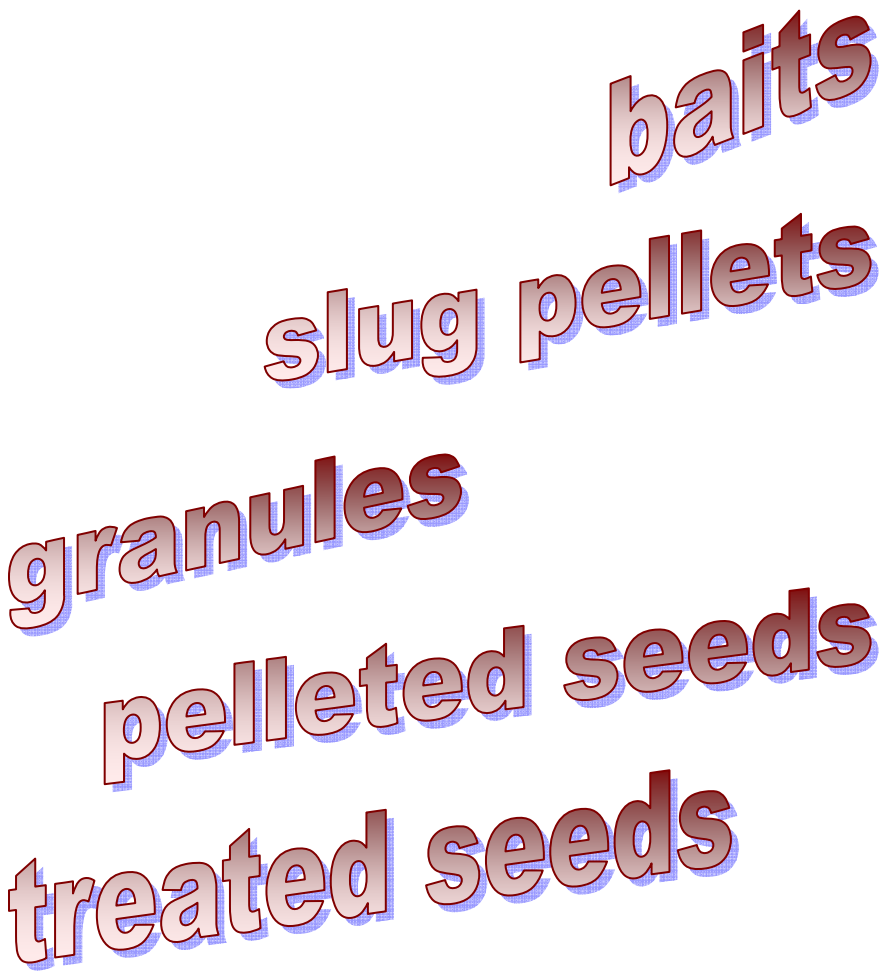
Non-spray applications

- Grouping of applications, definition of model species with worst-case exposure via diet and other routes
- Calculation of relevant concentrations for the ETE equation

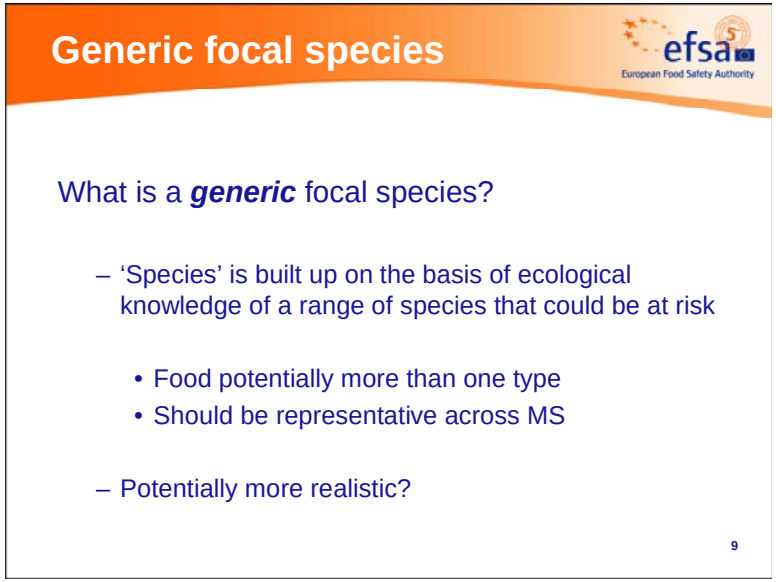


Options for refinement

- Generic tier-2 scenarios for specific crops and application times
- Measured residues and residue dynamics
- Identification of focal species as ecological representatives for birds or mammals potentially at risk
- Steps to refine the PT factor
- Steps to refine the information on composition of vertebrate diet (PD factor)
- Dehusking
- Avoidance
- Consideration of additional information on toxicity
- Refining the risk in the long-term scenario according to the phase-specific approach
- Further possibilities for refining the risk assessment

Generic tier 2

- Table of scenarios
- More extensive than tier 1
- Crops and application timings further specified
- Generic model species
- Typical dietary compositions



Residues and residue dynamics

- Measured residues and residue dynamics in plant food items
- Measured residues and residue dynamics in arthropod food items

Guidance for field experiments

- **It is intended to provide methodological recommendations how to perform arthropod residue studies under field conditions, considering:**
  - **Study site selection, plot size, replicates**
  - **Sampling methods for different strata (foliage, ground dwellers etc.)**
  - **Sample size and frequency (for determination of residue decline data)**
- **Recommendations may be provided as an annex / supplement to the new GD**

Will this be helpful for authorities (study interpretation) and notifiers / CRO's (study performance)?

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Identification of focal species

- Identification of focal species using targeted observation data
- Identification of focal species using other sources of information

An ideal 'focal species' should:

- Use the crop
  - high frequency of occurrence on crop fields
  - in significant numbers - high average density compared to other species
- Have a high food intake rate to body weight ratio
  - e.g. a small bird eating mainly leaves

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An ideal 'focal species' should:

- Eat food with high residues
  - e.g. the crop itself
- Be protective for other species
  - If the risk is considered acceptable for focal species it should follow that all other species are also protected

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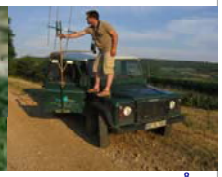
PT factor

- Criteria for performing radiotracking studies and evaluating observational data
- Use of other sources of information in refining PT

Overview on field methods

- It has not been possible so far to make direct measurements of the amount of treated food ingested by individual birds and mammals in the farming landscape
- by radiotracking, it is possible to make indirect estimates of PT
- Animals will be equipped with small radio transmitters, which allow continuous surveillance via radio signal





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How to analyse PT data?

Percentiles and Confidence bounds

- Because we wish to be protective in our risk assessments, we tend to use higher centiles (90^{th} or 95^{th}) rather than median values (50^{th})
- Radio-tracking is expensive, labour-intensive, and restricted by law. So sample size is often small
- But estimating 90^{th} centile from a small sample (say 10-20) entails a high degree of uncertainty
- We need to take this into account
- Use parametric bootstrap

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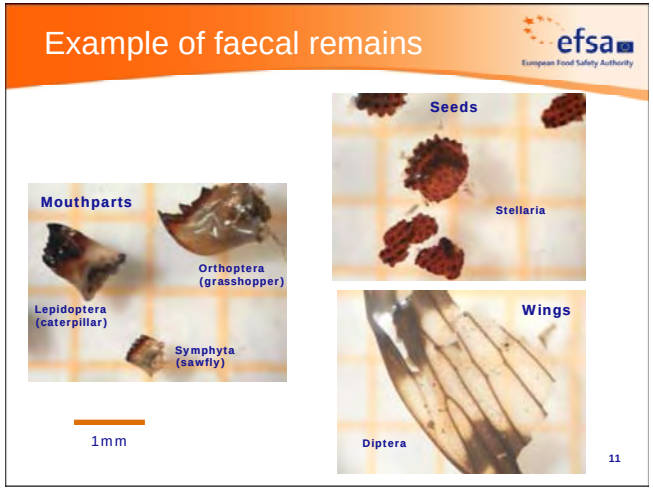
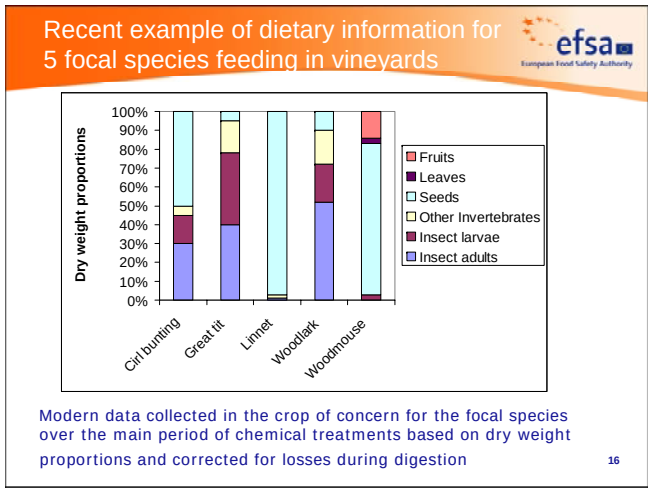
Composition of diet (PD factor)

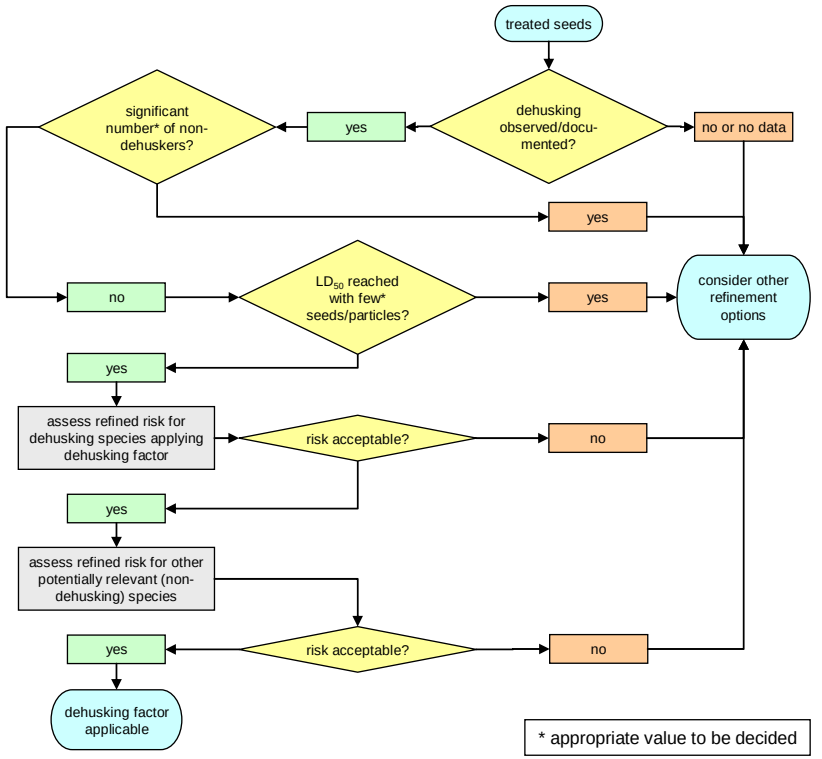
- Criteria for performing experimental food analyses and evaluating their results
- Use of other sources of information in refining the composition of vertebrate diet





Dehusking

- May reduce exposure (treated and pelleted seed scenarios)
- Applicability to be checked with regard to animal behaviour and substance properties
- Factors currently in use to be checked and probably revised



Additional information on toxicity

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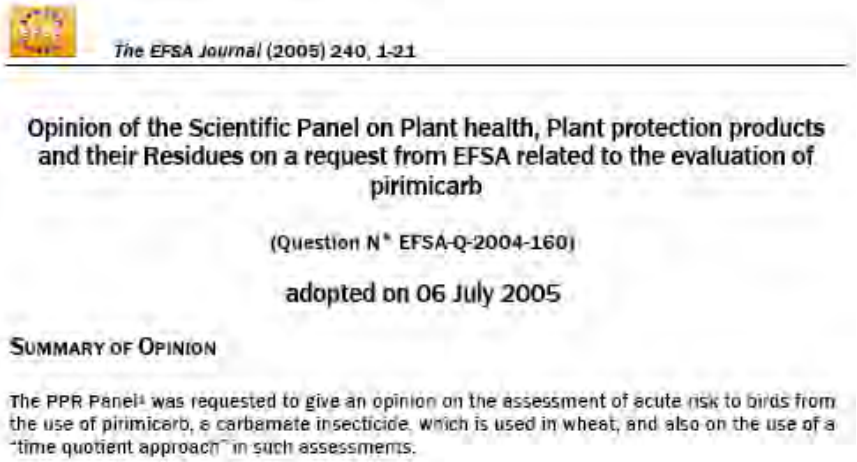
- Approaches to take account of the effects of avoidance and metabolism



The EFSA Journal (2005) 240, 1-21

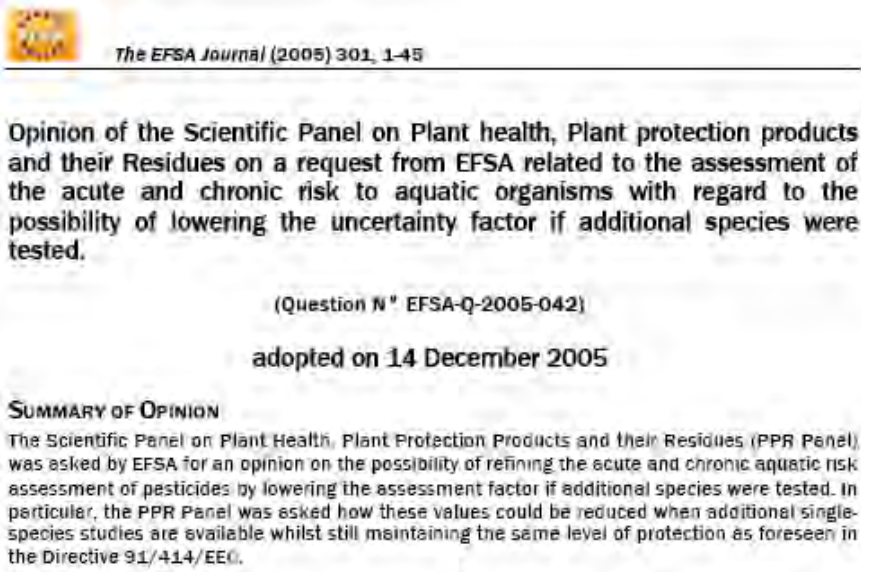
Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the evaluation of pirimicarb

(Question N° EFSA-Q-2004-160)

adopted on 06 July 2005

SUMMARY OF OPINION

The PPR Panel[1] was requested to give an opinion on the assessment of acute risk to birds from the use of pirimicarb, a carbamate insecticide, which is used in wheat, and also on the use of a "time quotient approach" in such assessments.



The EFSA Journal (2005) 301, 1-45

Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested.

(Question N° EFSA-Q-2005-042)

adopted on 14 December 2005

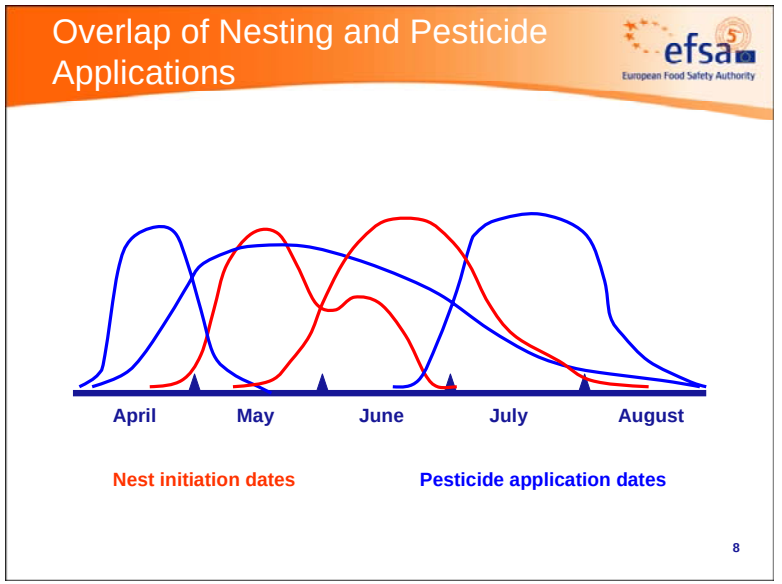
SUMMARY OF OPINION

The Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR Panel) was asked by EFSA for an opinion on the possibility of refining the acute and chronic aquatic risk assessment of pesticides by lowering the assessment factor if additional species were tested. In particular, the PPR Panel was asked how these values could be reduced when additional single-species studies are available whilst still maintaining the same level of protection as foreseen in the Directive 91/414/EEC.

- Uncertainty factors

Phase-specific long-term RA

- Review of toxicity endpoints
- Comparison of application dates and phases in breeding cycle
- Case-specific higher-tier refinements



Further possibilities

- Pen/cage studies
- Field tests
- Use of wildlife incident data
- Weight of evidence

RA using empirical model

- All relevant mechanisms contributing to the observed effects are intrinsically covered by the field studies.
- Quality and applicability depend on quality of field studies.
- Potential for extrapolation of results on other substances and effects must be assessed carefully.

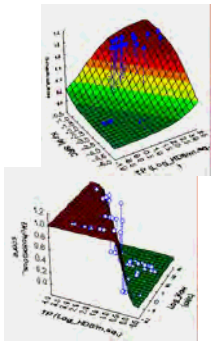
RA using empirical model

- Prediction of bird mortality on the acute time scale
  - Model equation and required input parameters
  - Options for refinement?

Analysis of avian field studies (4)

In addition to effect of toxicity:

- Indirect-acting substances: high K_{ow} increases risk
  - OPs requiring activation
  - **72% predicted correctly**
- Direct-acting substances: high K_{ow} decreases risk
  - Carbamates, OPs not requiring activation
  - **98% predicted correctly**



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Possible outcomes

1. No use of field study model – if unreliable
2. Use field study model to replace ETE-TER
   - for all substances, or
   - for selected substances (e.g. anticholinesterases)
3. Use field study model as a check for when to consider dermal exposure
4. Use field studies to calibrate ETE-TER approach

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Risk mitigation options

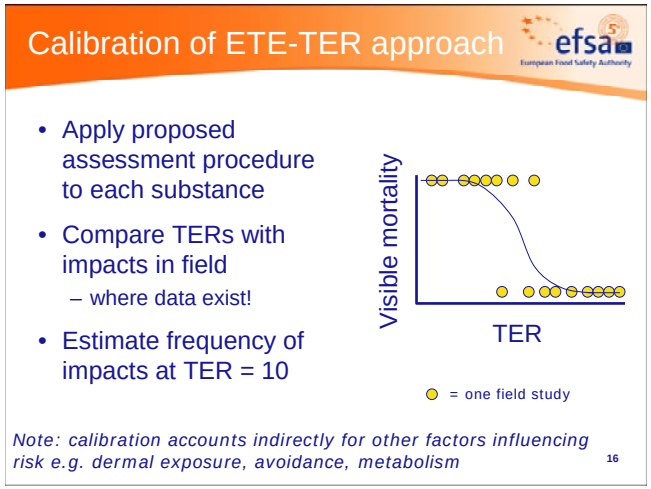
- Exposure-mitigating effect of precision-drilling
- Other options available?

Background document

- Residues of on food items for birds and mammals
  - Level of residues
  - Residue dynamics
- Bioaccumulation of chemicals in terrestrial vertebrates
- Field studies on bird mortality after pesticide applications
- Field studies on effects to small mammal populations after pesticide applications
- …

Supplementary document

- Worked examples
- Probabilistic risk assessment
- Calibration of ETE-TER approach
- Considerations on achieved level of protection
- Regulatory impact assessment
- …



… protective and usable

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